

REMARKS

In the Final Action dated January 29, 2003, claims 52-55 and 58-70 are pending and under consideration. Claims 62-67 are rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 1-12 of U.S. Patent 6,323,317, issued from the related application Serial No. 09/302,769. Claims 63-67 are further rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-10 and 13-15 of the '317 patent. Claims 52-55 and 58-70 are rejected under the written description requirement of 35 U.S.C. §112, first paragraph. Claims 52-55, 58 and 68-70 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by Schluter et al. (Mol. Reproductive Development 43: 1-6, January 1996). In addition, the application is objected to for allegedly improperly incorporating sequences by referring to accession numbers, e.g., at page 76.

Applicants filed a §1.116 Amendment on July 29, 2003, in which Applicants amended the claims and deleted the references to accession numbers at page 76 of the specification. In response, the Examiner issued an Advisory Action on October 24, 2003, stating that the §1.116 Amendment would not be entered, allegedly because that the deletion of the accession numbers at page 76 of the specification constitutes new matter by omission. The Examiner further indicated that the §1.116 Amendment, if entered, would overcome all rejections except the rejection of claim 52 under §102(a) based on Schulter et al. (GenBank Accession Z46940).

This Response addresses each of the Examiner's rejections and objections in the Final Action and in the Advisory Action. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

In the Final Action, the Examiner has objected to the application for certain alleged informalities. Specifically, the Examiner contends that the specification improperly incorporates sequences by referring to accession numbers, e.g., at page 76. The Examiner also points out that formal drawings will be required when the application is allowed.

During a telephone interview with the Examiner on December 1, 2003, the Examiner advised Applicants' representative that it is no longer necessary to include the actual sequences of the molecules designated by accession numbers. Therefore, Applicants respectfully request withdrawal of the objection to the specification based on the references to accession numbers. Applicants further respectfully submit that formal drawings will be submitted when the application is allowed. As such, withdrawal of the formality objections to the present application is respectfully requested.

Applicants further respectfully submit that the claims have been amended in an effort to expedite the prosecution of the present application. Applicants submit that the instant amendment to the claims is the same as the amendment to the claims, previously submitted in the §1.116 response. Specifically, claims 55, 58-62 and 64-67 have been canceled by way of the instant amendment. Claims 52-54, 63 and 68-70 have been amended. Claims 71-80 are added. New claim 71 is supported by original claim 53. New claims 72-74 are supported by original claim 54. New claims 74-76 are supported by original claims 59-61, respectively. New claims 77-78 are supported by original claim 63. New claim 79 is supported by original claim 64. No new matter is introduced by the instant amendment.

Claims 62-67 are rejected under 35 U.S.C. §101 in the Final Action as allegedly claiming the same invention as that of claims 1-12 of U.S. Patent 6,323,317 (the '317 patent), issued from the related application Serial No. 09/302,769.

Applicants respectfully submit that cancellation of claims 62 and 64-67 has rendered the rejection of these claims moot.

Claims 63 and 78-79, are directed to isolated proteins consisting of SEQ ID NO: 4, SEQ ID NO: 10 and SEQ ID NO: 12, respectively. Applicants observe that claims 1-12 of the '317 patent are directed to isolated proteins comprising a SOCS box (claims 1-12 of the '317 patent), which are further characterized as comprising certain specified amino acid sequences (claim 11 of the '317 patent), or encoded by certain specified nucleotide sequences (claim 12 of the '317 patent). Applicants respectfully submit that a statutory double patenting is proper only if the present application claims the same invention of the issued patent. One of the tests for determining whether the two sets of claims are directed to identical subject matter is to assess whether there is an embodiment that falls within one set of claims, but not the other set. See MPEP 804, IIA (page 800-20). In the instant case, there could be an isolated protein which comprises a SOCS box and meets the limitation of claims 1-12 of the '317 patent, and which does not meet the delineations of instant claims 63 and 78-79, drawn to isolated proteins consisting of SEQ ID NO: 4, SEQ ID NO: 10 and SEQ ID NO: 12, respectively. Therefore, it is respectfully submitted that claims 63 and 78-79 do not claim subject matter identical with claims 1-12 of the '317 patent.

In view of the foregoing, the statutory double patenting rejection of claims 62-67 under 35 U.S.C. §101 is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 63-67 are further rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-10 and 13-15 of the '317 patent.

Applicants respectfully submit that cancellation of claims 62 and 64-67 has rendered the rejection of these claims moot. With respect to claim 63 and new claims 78-79, Applicants provide herewith a copy of the terminal disclaimer submitted in the §1.116 response on July 29, 2003, which has disclaimed the term of the patent issuing from the present application that is beyond the term of the '317 patent. As such, Applicants respectfully submit that the obviousness-type double patenting based on the '317 patent is overcome. Withdrawal of the rejection is respectfully requested.

Claims 52-55 and 58-70 are rejected under the written description requirement of 35 U.S.C. §112, first paragraph. The Examiner has suggested that Applicants include a specific function of the claimed molecule in the claims, e.g., "wherein said protein inhibits IL-6-mediated signal transduction", to overcome the rejection.

Applicants respectfully submit that cancellation of claims 55, 58-62 and 64-67 renders the rejection of these claims moot. Claims 53-54, 63 and 70, and new claims 71-80, all recite specific sequences, and therefore fully comply with the written description requirement of 35 U.S.C. §112, first paragraph. As to claims 52 and 68 (and dependent claim 69), these claims have been amended such that the SOCS protein is further characterized as inhibiting IL-6 mediated signal transduction. Therefore, the isolated nucleic acid molecules and proteins, as presently claimed, fully satisfy the written description requirement under 35 U.S.C. §112, first paragraph. Accordingly, withdrawal of the rejection under the written description requirement under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 65-66 are rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for using the term "modulate".

It is respectfully submitted that cancellation of claims 65-66 renders the rejection thereof moot. Withdrawal of the rejection is respectfully requested.

Claims 52-55, 58 and 68-70 are rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Schluter et al. (*Molecular Reproductive Development* 43: 1-6, January 1996).

According to the Examiner, Schluter et al. teach a nucleic acid sequence of Z47352 which has 98.6% identity to instant SEQ ID NO: 3 (murine SOCS1); a nucleic acid sequence of Z46940 which has 99.3% identity to instant SEQ ID NO: 9 (human SOCS1); and a nucleic acid sequence of Z46939 which has 100% identity to instant SEQ ID NO: 11 (rat SOCS1).

From the partial Genbank sequence reports provided by the Examiner, Applicants observe that the nucleic acid molecules having the accession number Z47352, Z46940 and Z46939 are large molecules of 13812bp, 28535bp and 13187bp in length ("bp" denotes "base pair"), respectively. On the other hand, the instant SOCS1 nucleotide sequences are only 1235 bp (murine), 1094 bp (human) and 2087 bp (rat), respectively. The sequence alignment, which has been provided by the Examiner, shows that instant SEQ ID NO: 3 (murine SOCS1, 1235 bp) has 98.6% identity to a 1226 bp portion of the nucleic acid molecule Z47352; that instant SEQ ID NO: 9 (human SOCS1, 1094bp) has 99.3% identity to a 1089bp portion of the nucleic acid molecule Z46940; and that instant SEQ ID NO: 11 (rat SOCS1, 2807bp) bears 100% identity to a 2807bp portion of the nucleic acid molecule Z46939.

Applicants previously argued that the Examiner has not shown that the sequences of Schluter et al. were made available prior to the priority date of the present application (November 1996). The Examiner responded in the Advisory Action that she could only take into consideration the publication date of Schluter et al., which is January 1996.

However, Applicants also submitted that assuming, *pro arguendo*, that Examiner has established that Schluter et al. is a proper prior art reference under §102(a), the claims as amended are not anticipated by Schluter et al.

Specifically, Schluter et al. do not teach a nucleotide sequence as set forth in SEQ ID NO: 3 (murine SOCS1) or SEQ ID NO: 9 (human SOCS1), or a nucleotide sequence encoding the murine SOCS1 protein (SEQ ID NO: 4) or human SOCS1 protein (SEQ ID NO: 10). Therefore, Applicants respectfully submit that claims 53-54 and 70-73, as well as claims 75-77 insofar as claims 75-77 relate to SEQ ID NO: 3, 4, 9 or 10, are not anticipated by Schluter et al.

Applicants further respectfully submit claim 74, directed to an isolated nucleic acid molecule consisting of SEQ ID NO: 11, and claims 75-77 insofar as these claims depend from claim 74, are not disclosed by Schluter et al.

With respect to claims 68-69, these claims are presently directed to an isolated nucleic acid molecule consisting of a SOCS protein coding sequence. It is respectfully submitted that Schluter et al. merely teach large fragments of nucleic acid molecules. There is no recognition or teaching of isolated nucleic acid molecules consisting of a SOCS protein coding sequence. Therefore, it is respectfully submitted that claims 68-69 are not anticipated by Schluter et al.

The Examiner stated in the Advisory Action that the §1.116 amendment, if entered, would overcome all rejections except the rejection of claim 52 under §102(a) based on Schluter et al. The Examiner maintained that she considered the Schluter et al. reference to have been published in January 1996, before the priority date of the present application of November 1996.

Applicants reassert that the full-length sequences of Schluter et al. were not made available to the public prior to November 1996. However, assuming, *pro arguendo*, the full-

length sequences of Schluter et al. were available to the public prior to November 1996, Applicants respectfully submit that Schluter et al. still do not teach the nucleic acid molecule of claim 52.

More specifically, claim 52, as presently amended, is directed to an isolated nucleic acid molecule comprising a nucleotide sequence which encodes a protein, wherein the protein comprises a SOCS box which comprises the amino acid sequence as set forth in SEQ ID NO: 55. SEQ ID NO: 55 sets forth the SOCS box motif of the human SOCS1 protein of SEQ ID NO: 9.

Schluter et al. allegedly teach a nucleic acid sequence of Z46940, which has 99.3% identity to instant SEQ ID NO: 9 (human SOCS1). Applicants observe that in the Genbank Sequence Report of Z46940 (attached hereto as **Exhibit 1**), Schluter et al. allege that the portion of the nucleic acid sequence of Z46940, i.e., nucleotide number 27369-28004, represents the open reading frame of SOCS-1. However, the amino acid sequence of SOCS-1 given by Schluter et al. in the Sequence Report is not identical to the human SOCS1 of SEQ ID NO: 10 of the present application. In particular, the SOCS box motif of the SOCS1 protein of Schluter et al. has the sequence of "VRPLQELFR.....DYL", whereas the SOCS box motif of the human SOCS1 protein of the present application comprises the sequence "VRPLQELCR.....DYL" (SEQ ID NO:55). Therefore, Applicants respectfully submit that Schluter et al. do not teach a nucleic acid molecule encoding a protein which comprises the SOCS box sequence of SEQ ID NO: 55, as presently claimed.

Accordingly, it is respectfully submitted that the rejection based on Schluter et al. under §102(a) is overcome. Withdrawal of the rejection is therefore respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. S. DiGiglio', written in a cursive style.

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Enc.:
Copy of the Terminal Disclaimer filed July 29, 2003;
Exhibit 1: Genbank Sequence Report of Z46940.